

## REMARKS

Claim 5 has been amended to correct a typographical error. No new matter has been added as a result of this amendment.

The Office has restricted claims in this case to four distinct inventions designated as follows:

- Invention I, claims 1-42 and 51-54, drawn to a method, system and computer-readable medium for assessing and managing risk associated with utilizing a pharmaceutical product, classified in class 705;
- Invention II, claims 43-50, drawn to a method of creating educational materials for use in mitigating the risks of a pharmaceutical product, classified in class 705, subclass 2;
- Invention III, claims 55 and 56, drawn to a pharmaceutical product risk assessment and management kit, classified in class 704, subclass 2; and
- Invention IV, claim 57, drawn to a pharmaceutical product hazard scoring chart, classified in class 705, subclass 2.

Applicant respectfully traverses the Restriction Requirement and requests reconsideration. In order to be fully responsive, Applicant has provisionally elected, with traverse, Invention I as defined by claims 1-42 and 51-54 directed to a method, system and computer-readable medium for assessing and managing risk associated with utilizing a pharmaceutical product.

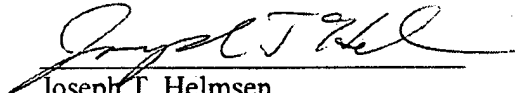
It is respectfully submitted that the search classification for each invention group will substantially overlap. Even if the Office still considers the groups of claims to be patentably distinct, MPEP §803 mandates two criteria for a proper requirement for restriction: 1) the inventions must be independent or distinct; and 2) there must be a serious burden on the examiner. For purposes of initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in M.P.E.P. §808.02. Significantly, the Examiner has not met the *prima facie* burden. Indeed, each Invention is listed by the Examiner to be within the same class and subclass. The Examiner will not be seriously burdened by searching and considering the inventions as described in all the currently pending claims. Accordingly, the Examiner has not established a proper restriction requirement under MPEP§ 803.

By this election, Applicant does not admit, nor does Applicant waive the right to argue against at a later date, the Office's statement that the groups of inventions are patentably distinct. Applicant expressly reserves the right to present the claims of Inventions II-IV or other claims, in one or more divisional, continuation, or continuation-in-part applications at a later date.

**AUTHORIZATION**

No fees other than those listed above are believed to be due for this submission. However, the Commissioner is hereby authorized to charge any additional fees which may be required for this Response, or credit any overpayment, to deposit account no. 50-0436.

Respectfully submitted,  
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